**Questions and Answers about Emergency Use Instructions (EUI)**
Below are answers to frequently asked questions about Emergency Use Instructions (EUI). Refer to EUI for Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine for primary, additional, and/or booster doses.

**What are Emergency Use Instructions (EUI)?**
Emergency Use Instructions (EUI) allow CDC to inform healthcare providers and recipients about certain uses of medical products approved (licensed) by the U.S. Food and Drug Administration (FDA) that are needed during public health emergencies without the FDA needing to issue an Emergency Use Authorization (EUA). The CDC Director has legal authority to create, issue, and disseminate EUI before or during an emergency for FDA-approved medical products with instructions to inform healthcare providers and recipients about such products' approved, licensed, or cleared conditions of use under circumstances that go beyond the scope of the approved labeling (package insert).

**What EUI did CDC issue and why?**
CDC has issued EUI for use of the COVID-19 vaccine by Pfizer-BioNTech and COVID-19 vaccine by Moderna for primary, additional, and/or booster doses in certain individuals. The EUI are necessary because these uses extend beyond their FDA-approved labeling. The EUI and CDC's clinical guidance help to ensure these individuals can get primary, additional, and/or booster doses of the COVID-19 vaccine by Pfizer-BioNTech or Moderna so they can be better protected against COVID-19.

The EUI are currently issued only for Pfizer-BioNTech and Moderna COVID-19 vaccines since EUI can only apply to FDA-approved medical products. The following describes why CDC issued EUI for the Pfizer-BioNTech and Moderna COVID-19 vaccines.

- CDC issuance of initial EUI for the COVID-19 vaccine by Pfizer-BioNTech on November 17, 2021

  CDC issued initial EUI for the COVID-19 vaccine by Pfizer-BioNTech[1] and updated its interim clinical considerations on November 17, 2021 to ensure that certain people who were vaccinated outside of the United States, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in a clinical trial, can get an additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech. CDC issued EUI to allow additional primary doses of the COVID-19 vaccine by Pfizer-BioNTech in certain immunocompromised individuals 12 years and older and a heterologous booster dose in persons 18 years and older 6 months after completion of primary series vaccination with certain vaccines not FDA-authorized or approved.

  The EUI for the COVID-19 vaccine by Pfizer-BioNTech were amended, subsequent to the initial EUI issuance, for the following:
  - expanded the age of heterologous booster doses to 16 years and older following primary series vaccination at least 6 months previously with certain vaccines not FDA-authorized or approved in the United States[2] on December 9, 2021.
  - updated the eligible age of booster doses to 12 years and older, booster dose interval to 5

[1] The COVID-19 vaccine by Pfizer-BioNTech (brand name Comirnaty) was approved by FDA in August 2021 as a 2-dose primary series for active immunization to prevent COVID-19 in persons ≥ 16 years. FDA also amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to authorize an additional primary dose in certain immunocompromised persons ≥ 12 years and a homologous or heterologous booster dose in persons ≥ 18 years following primary vaccination with the Pfizer-BioNTech or a different FDA-authorized COVID-19 vaccine.

[2] FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine on December 9, 20201 to expand the eligible population for homologous booster doses to persons ≥ 16 years.

months, vaccine use for those with incomplete primary dose series of non-FDA-authorized or approved COVID-19 vaccines, and included the new FDA-approved formulation of the vaccine for persons 12 years and older (gray-capped multi-dose vials) on January 7, 2022.

- in concert with CDC interim clinical considerations, EUI were updated on February 11, 2022 to allow an additional Pfizer-BioNTech COVID-19 vaccine dose in persons 18 years and older with certain immunocompromising conditions who received primary vaccination with the Janssen COVID-19 vaccine; revaccination of certain moderately or severely immunocompromised persons 12 years and older who received certain therapies (i.e., hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy) and received COVID-19 vaccine prior to or during treatment; and the ability of healthcare providers to administer the Pfizer-BioNTech COVID-19 vaccine outside of the FDA-authorized or FDA-approved labeling and CDC recommended dosing intervals based on clinical judgment when the benefits of vaccination are deemed to outweigh the potential and unknown risks.

- extended the dosing interval to 8 weeks* between the first and second primary doses of Pfizer-BioNTech COVID-19 vaccine on February 22, 2022.

- CDC issuance of initial EUI for the COVID-19 vaccine by Moderna on February 11, 2022
  With the FDA's approval of the COVID-19 vaccine by Moderna (brand name Spikevax) on January 31, 2022 as a two-dose primary series for active immunization to prevent COVID-19 in persons 18 years and older, the vaccine became eligible for EUI. CDC issued EUI for the Moderna COVID-19 vaccine to allow primary, additional, and/or booster doses in persons 18 years and older, including those vaccinated with certain non-FDA authorized or approved COVID-19 vaccines and certain individuals with immunocompromising conditions, similar to the uses that go beyond or differ from the FDA-approved labeling as described in the EUI for the Pfizer-BioNTech COVID-19 vaccine.

  The EUI for the COVID-19 vaccine by Moderna were amended, subsequent to the initial EUI issuance, for the following:
  - extended the dosing interval to 8 weeks* between the first and second primary doses of Moderna COVID-19 vaccine on February 22, 2022.

**What are the risks and benefits of the COVID-19 vaccines by Pfizer-BioNTech and Moderna?**
Available data on the safety or efficacy of additional primary or booster doses of COVID-19 vaccines by Pfizer-BioNTech or Moderna after receipt of a non-FDA authorized or approved COVID-19 vaccine are limited. However, based on available information, the known and potential risks of primary, additional, and/or booster doses of the COVID-19 vaccines by Pfizer-BioNTech or Moderna might be outweighed by their likely benefit to enhance or restore protection by the primary vaccination, which might have waned over time. Refer to the EUI Fact Sheets for Healthcare Providers for Pfizer-BioNTech and Moderna and Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information.

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*The originally recommended interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second primary doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease.